

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
 PELVIC REPAIR SYSTEMS
 PRODUCT LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert Motion re: Juan Carlos Felix, M.D.*)

Pending before the court is the Motion to Preclude Testimony of Defense Expert Juan Carlos Felix, M.D. [ECF No. 2063] filed by the plaintiffs. The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”), among others.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.¹

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties’ misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert’s* core considerations for assessing expert

¹ The plaintiffs identified the Wave 1 cases affected by this Motion in their attached Exhibit A [ECF No. 2063-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert

testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of “junk science” looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court’s prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—and I will therefore reserve ruling until the expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these

standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Felix is a board-certified anatomic pathologist with added qualification in cytopathology. The plaintiffs object to his proposed testimony on several grounds.

a. General Opinions

The plaintiffs first seek to exclude Dr. Felix's opinions in their entirety because both Dr. Felix's experience and review of the scientific literature is insufficient to render his opinions reliable. As to Dr. Felix's experience, the plaintiffs argue that Dr. Felix's review of over 50 mesh specimens over the course of 22 years is insufficient to establish reliable opinions because Dr. Felix relies solely on his memory. The plaintiffs point out that Dr. Felix reviewed the majority of the mesh specimens around the year 2000. The plaintiffs argue that Dr. Felix's opinions should be excluded because his "recollections cannot be confirmed, tested, or rebutted." Mem. Supp. Mot. re: Dr. Felix 7 [ECF No. 2069]. I am without sufficient information to determine the reliability of Dr. Felix's opinions based on his concept of what a "typical" mesh specimen looks like. The sole basis of Dr. Felix's experience-based opinions appears to be his review of 50 mesh slides over a period of 22 years, and I have no information regarding Dr. Felix's criteria for collecting, evaluating, and testing his examined mesh slides. According, I **RESERVE** ruling on the plaintiffs' Motion on this point.

Next, the plaintiffs argue that Dr. Felix cites to "almost" no scientific literature, studies, or other support for his criticisms of Dr. Iakovlev. In essence, the plaintiffs argue that defense counsel's hand-picking of articles does not qualify as a literature review under *Daubert*. Upon a review of the plaintiffs' cited deposition testimony, however, Dr. Felix specifically stated that Ethicon turned over its internal

documents once Dr. Felix requested them. No part of the plaintiffs' cited-to deposition indicated that Dr. Felix failed to examine sufficient facts and data to support his opinions. Dr. Felix's reliance list is replete with citations to scientific literature regarding mesh devices. The plaintiffs' Motion is **DENIED** on this point.

b. Degradation

Next, the plaintiffs challenge the reliability of Dr. Felix's opinion that polypropylene does not degrade *in vivo*, which the plaintiffs allege is premised on speculative assumptions and a flawed review of the literature.

In response, Ethicon indicates it "will not elicit testimony from Dr. Felix on the question of whether or not Prolene degrades." Resp. 8 [ECF No. 2184]. Yet, Ethicon also indicates that Dr. Felix "will testify that there is no support—in the medical literature or in the histological slides he has reviewed—for the notion that any alleged degradation has any clinical significance." Resp. 9. I do not interpret Ethicon's response to entirely concede the plaintiffs' challenge as to degradation-related opinions. Additionally, although personal experience and a review of the medical literature are reliable bases on which to form an expert opinion in the abstract, the court is unable to judge the reliability of Dr. Felix's observations without more information about his methodology. *Compare Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."), *with Fed. R. Evid. 702* advisory committee's note to 2000 amendment ("If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached,

why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.”).

I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony based primarily on a doctor’s experience *not* observing something. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

c. Reliance on Dr. Steven MacLean

The plaintiffs also ask that Dr. Felix’s testimony be excluded to the extent he relied on Dr. MacLean. The plaintiffs provide no specific argument, but refer to several other documents and motions which they “adopt and incorporate” into the instant Motion. Mem. 11. Without more, the court is unable to appropriately consider the plaintiffs’ arguments so their Motion on this point is **DENIED**.

d. Contracture

The plaintiffs also challenge the reliability of Dr. Felix’s opinions on contracture, specifically that TVT mesh does not contract *in vivo*. Mem. 12. Again, Ethicon responds that Dr. Felix “does not seek to opine that Ethicon’s mesh products cannot contract” but nonetheless acknowledge that Dr. Felix will testify “that he has not observed these complications in his analysis of mesh explants in his practice or in this litigation, and that two large-scale reviews support his opinion.” Resp. 10–11. As above, I do not interpret this response as a concession to the plaintiffs’ challenge. And although personal experience and a review of the medical literature are reliable bases on which to form an expert opinion in the abstract, the court is unable to judge the reliability of Dr. Felix’s observations without more information about his

methodology. *See* Fed. R. Evid. 702 advisory committee's note to 2000 amendment. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

e. Cytotoxicity

The plaintiffs seek to exclude Dr. Felix's opinions regarding cytotoxicity as unreliable. Ethicon acknowledges that Dr. Felix will opine that he has never seen any evidence that TVT is cytotoxic *in vivo*, which Ethicon claims is based on Dr. Felix's review of Dr. Iakovlev's photomicrographs, Dr. Felix's clinical experience, and a review of the relevant medical literature. Resp. 14. Again, although these are reliable bases on which to form an expert opinion in the abstract, the court is unable to judge the reliability of Dr. Felix's observations without more information about his methodology. *See* Fed. R. Evid. 702 advisory committee's note to 2000 amendment. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

f. Complications

The plaintiffs next challenge Dr. Felix's opinion regarding whether TVT causes pain. In his report, Dr. Felix states that he had an opportunity to examine over 50 mesh explants and that, "to his knowledge," none of the women who received the explants were experiencing pain at the time of their surgery. Felix Report 19 [ECF No. 2063-2]. In essence, the plaintiffs seek to exclude Dr. Felix's inference that Dr. Iakovlev could not have made a finding that mesh causes pain based on Dr. Iakovlev's review of slides that were histologically identical to the ones Dr. Felix observed because, to Dr. Felix's knowledge, the women who received explants and whose slides

Dr. Felix observed did not experience pain.

An expert does not offer a sufficiently reliable scientific opinion simply by stating that something is a fact to the best of his knowledge. *Daubert* requires me to take more than just an expert's word for it. Dr. Felix failed to explain why he believes that certain women did not experience pain before their explant surgery, and Dr. Felix failed to even indicate whether he performed any of the surgeries. Yet, he relies on his *understanding* that certain women did not experience pain to extrapolate generally to all women with mesh devices. Dr. Felix's opinion on this point is unreliable, and it is **EXCLUDED**.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible

prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 (“[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value.”). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors “to erroneously conclude that regulatory compliance proved safety.” *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon’s compliance with or violation of the FDA’s labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon’s compliance with design control and risk management standards. Some of this testimony involves the FDA’s quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and

document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of

these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g., United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer

testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

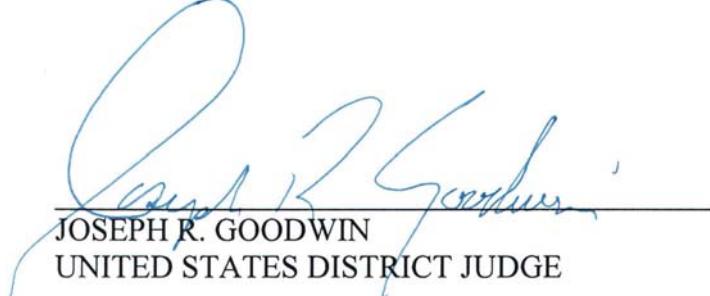
Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering testimony the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court DENIES in part, GRANTS in part, and RESERVES in part the Motion to Preclude Testimony of Defense Expert Juan Carlos Felix, M.D. [ECF No. 2063].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: August 31, 2016



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

A handwritten signature in blue ink, appearing to read "Joseph R. Goodwin", is written over a horizontal line. Below the signature, the name "JOSEPH R. GOODWIN" is printed in capital letters, followed by "UNITED STATES DISTRICT JUDGE" on a new line.

EXHIBIT A

FELIX

THIS DOCUMENT RELATES TO PLAINTIFFS:

Dina Destefano-Raston
2:12-cv-01299

Kathleen Wolfe
2:12-cv-00335

Constance Daino
2:12-cv-01145

Cindy Smith
2:12-cv-01149

Sherry Fox
2:12-cv-00878

Dina Sanders Bennett
2:12-cv-00497

Patricia Ruiz
2:12-cv-01021

Donna Loustaunau
2:12-cv-00666

Patti Ann Phelps
2:12-cv-011731

Teresa Georgilakis
2:12-cv-00829

Donna Hankins
2:12-cv-01011

Paula Kriz
2:12-cv-00938

Miranda Patterson
2:12-cv-00481

Jennifer Sikes
2:12-cv-00501

Krystal Teasley

2:12-cv-00500